

REMARKS/ARGUMENTS

Applicants appreciate the telephone conversation with the Examiner on June 10, 2005. This is in response to the Office Action mailed June 1, 2005. Claim 1 has been amended to clarify that the metabolic change includes weight loss. Claim 51 has been amended to include alternative terminology. Support for these amendments can be found throughout the originally filed application, e.g., page 3, lines 20-21 and page 10, line 11. No new matter is introduced and these are not narrowing amendments. Independent claim 1 and its dependent claims 4-6, and 27-49 and independent claim 50 and its dependent claims 51-60 are currently pending and at issue.

Applicants respectfully object to the issuance of a final office action because new grounds of rejections have been raised. Therefore, Applicants request that the status of this action be deemed non-final.

Claim Rejections - 35 U.S.C. §102

The Examiner has maintained rejections against claims 1, 5, 6, 28 and 47-49, and raised rejections against claims 50-53 under 35 U.S.C. §102(e) as being anticipated by Hinz. The Examiner asserts that Hinz teaches calcium for the treatment of obesity and that a generic multiple vitamin is disclosed (column 8, line 65). The Examiner further asserts that "Hinz contemplated a direct effect by calcium on weight reduction" based on the conclusion of column, 4, line 27 regarding the statement "and effecting weight loss."

However, Applicants reaffirm that Hinz does not teach, disclose or suggest intentionally using or administering calcium in order to induce a metabolic change, such as weight loss, as set forth by the present claims. The Examiner has selected various fragments from the disclosure of Hinz and has inappropriately concluded that Hinz teaches use of calcium for inducing a

metabolic change, that includes weight loss.

First, the comprehensive pharmacologic therapy of Hinz is intended to bring about weight loss by appetite suppression and not by a metabolic change as set forth in the present claims. For example, "[a] principal object of [Hinz] is the provision of a comprehensive pharmacologic therapy for treatment of obesity of relatively simple and inexpensive design which fulfills the intended purpose of appetite suppression to enable weight loss without fear of injury to persons" (column 2, lines 50-54, emphasis added).

Second, the active ingredients that Hinz provides for the appetite suppression do not include calcium, e.g.,

The comprehensive pharmacological therapy for treatment of obesity involves the combination of medications within "effective dosing ranges" and "optimal dosing ranges". The weight loss therapy in general involves the use of effective dosing ranges of Citalopram and Phentermine; Citalopram and Diethylpropion; Citalopram, Phentermine, and Diethylpropion to effectuate weight loss in a patient.

(column 4, lines 59-65, emphasis added). Therefore, Hinz contemplates Citalopram and Phentermine; Citalopram and Diethylpropion; Citalopram, Phentermine, and Diethylpropion, and not calcium, to effectuate weight loss.

Thirdly, Hinz includes the use of various replacement vitamins to counter nutritional deficiency, e.g.,

The use of Citalopram, Phentermine, and Diethylpropion in effective dosing ranges as well as optimum dosing ranges in conjunction with proper replacement of vitamins to counter nutritional deficiency successfully resolves two problems unique to weight loss management programs which use medications. The use of Citalopram, Phentermine, and Diethylpropion in conjunction with nutritional supplements in effective dosing ranges generally achieves acceptable weight loss performance for all patients thereby eliminating the failure of the weight loss program to be effective for five percent to eight percent of the patients who have initiated medication therapy.

(column 5, line 66-column 5, line 9, emphasis added). Hinz contains these vitamins, such as calcium, to avoid certain deficiencies, and not because they contribute to inducing weight loss, e.g.,

In order to avoid a Serotonin and/or Norepinephrine deficiency a patient under the comprehensive pharmacological therapy for treatment of obesity receives a generic multiple vitamin, 5-Hydroxytryptophan in a range of 50 mg to 900 mg per day, vitamin B6 in a range of 2 mg to 150 mgs per day, vitamin C in a range of 50 mg to 2000 mg per day, and Tyrosine in a range of 50 mg to 4000 mgs per day, as well as calcium in a range of 50 mg to 2000 mgs per day to prevent bone demineralization and Lysine in a range of 50 mg to 2000 mgs per day which is used to prevent hair loss and other protein metabolism problems while a patient is in a medically induced starvation state of weight management.

(column 5, line 62- column 6, line 7, emphasis). Hinz' use of calcium, as stated above, is to prevent bone demineralization.

Finally, under the Summary of the Invention, Hinz lists various paragraphs of objectives and features describing the "comprehensive pharmacologic therapy," some which include a listing of the active ingredients included in "effective therapeutic range for a patient to effectuate weight loss" (e.g., column 3, lines 46-61, emphasis added), and others which include a listing of the vitamin included in "an effective therapeutic range to assist in avoiding nutritional deficiency and effectuating weight loss" (column 3, lines 62-column 4, line 40, emphasis added). As set forth in Hinz, the former category of active pharmacologic agents is stated as to effectuate weight loss, in contrast to the latter category of vitamins, which is stated to assist in avoiding nutritional deficiency and effectuating weight loss as caused by the active pharmacologic agents.

Hinz repeats essentially this same language several times, e.g., "[s]till another feature of the present invention is the provision of a comprehensive pharmacologic therapy for treatment of obesity which includes the consumption of calcium by a patient in an effective therapeutic range to assist in avoiding nutritional deficiency and effectuating weight loss" (column 4, lines 25-27, emphasis added). These passages reinforce the interpretation that Hinz does not teach

administering calcium thereby inducing weight loss, but rather Hinz uses calcium to prevent bone demineralization.

Therefore, as set forth above, the Examiner's contention that Hinz contemplates the use of calcium to induce weight loss is unfounded and inconsistent with the Hinz reference.

Again, the present invention is directed to the use of therapeutically effective amounts of calcium or calcium-containing products, such as dairy products, thereby inducing weight loss via a calcium-induced metabolic change. Hinz does not teach such a method, explicitly or inherently. The use of pharmaceuticals and calcium suggested by Hinz, especially in low amounts, would not necessarily and inevitably induce the metabolic change as recited in claim 1 or 50 and their dependent claims.

Accordingly, claims 1, 4-6, 27-60 are not anticipated.

Claim Rejections - 35 U.S.C. §103

The Examiner has maintained rejections against claims 1, 4-6, and 27-49, and raised rejections against claims 54-60 under 35 U.S.C. §103(a) as obvious in light of Hinz. The Examiner states that Hinz is described as set forth above and that it does not teach the various claimed natural and manufactured products. The Examiner reiterates that as to the claimed food vehicles, such as spinach, or items that may be fortified with such are well known to be a source of calcium in the diet, and that it would be obvious to substitute a food source for the multivitamin disclosed in Hinz, for the beneficial effect of the additional nutrient therein. The Examiner further purports that as to the claimed restriction of caloric intake that would also be obvious to the layman as an enhancement to the method of Hinz to achieve an additional or more rapid loss of weight.

As set forth above, Applicants contend that Hinz does not teach or suggest the use of

calcium to induce weight loss. Nor would it be obvious to one skilled in the art to administer calcium or calcium-containing products, such as dairy products, and thereby to induce weight loss. To the contrary, Hinz's reliance on active pharmacologic agents teaches away from using calcium as a weight loss agent.

In addition, the Examiner contends that the nexus connecting the previously submitted evidence and applicants' claimed invention is unclear and that commercial success may be a result of marketing rather than the non-obviousness of the claimed method. However, this evidence was not submitted simply to prove commercial success, but rather to show that calcium's role in inducing weight loss was unrecognized and unexpected. Applicants reiterate that prior to Dr. Zemel's work, there was no recognition that high calcium dosages in the claimed food vehicles or the diet would be therapeutically effective to promote weight loss. The importance of maintaining high calcium intake during attempts to lose, maintain or control weight was previously unrecognized and was unexpected prior to Dr. Zemel's pioneering work.

The evidence shows that due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The invention has achieved considerable public recognition and commercial success, as indicated by the attached documentation.

Applicants further contend that even with widespread recognition, the claimed method is so unexpected that there remains skepticism about the effects of calcium/dairy on weight loss. For example, there have been advertisements asserting that Yoplait yogurt promotes weight loss (advertising claims that are subject to a license agreement under the present patent application). A challenge was filed by an anonymous party, who argued that there was no support for the claim

that calcium consumption promotes weight loss. The challenger apparently still doubts the efficacy of the invention as claimed in the present application. The National Advertising Division (NAD) of the U.S. Better Business Bureau ruled that the evidence (research by Dr. Zemel) supported General Mills' advertisement of the weight loss benefits of the calcium-containing dairy product (decision attached). This dispute, and its conclusion accepting the surprising evidence of the weight loss efficacy of calcium, further evidences the non-obviousness of the claimed invention.

Accordingly, claims 1, 4-6, 27-49 and 54-60 are not obvious.

Disclosure Objection

The disclosure was objected to because of an informality. On August 27, 2004, Applicants amended the specification on page 20, in Table 4, and so the objection is moot, as discussed with the Examiner during the telephone conversation of June 10, 2005.

Claim Rejections - 35 U.S.C. §112

Claim 57 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. However, as discussed above, on August 27, 2004, applicants submitted an amendment to table 4. Therefore the rejection of claim 57 is moot, as discussed with the Examiner during the telephone conversation of June 10, 2005.

Claim Rejections - 35 U.S.C. §§ 101 and 112

Claim 51 has been rejected claim 51 under U.S.C. 101 and 112 because its subject matter is allegedly inoperative and therefore lacks utility and enablement. The Examiner asserts that there is no evidence that the claimed method can prevent weight gain and that there are no parameters against which the claimed effect of prevention can be tested. Claim 51 has been amended to replace the term "preventing" with the phrase "attenuating, controlling and/or reducing" which should render the rejections moot, as discussed with the Examiner during the telephone conversation of June 10, 2005. The application states that by using the prescribed method of administering calcium to induce weight loss, then weight gain can be attenuated, controlled or reduced. One of ordinary skill in the art would readily understand and be able to practice the invention to achieve the prescribed results.

Applicants respectfully submit that their application is now in condition for allowance. Should any questions remain, please contact the undersigned.

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Respectfully submitted,



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Dc2/655493

Case #4174 (04/22/04)

GENERAL MILLS, INC.

Yoplait Light Yogurt

Advertising Agency:

Challenger:



Saatchi & Saatchi

National Advertising Division

- Establishment claims require reliable and well controlled clinical testing on the product in question that can be readily verified to substantiate the claims.

Basis of Inquiry: NAD requested substantiation for certain nutrition and weight loss claims made by General Mills, Inc. in a broadcast commercial for its Yoplait Light Yogurt as part of its routine monitoring program. The commercial features a woman of average weight who paces back and forth while eating Yoplait Light Yogurt (in front of a window showing the passing of the seasons) looking at a yellow polka dot bikini, placed on a hanger on a wall, that she clearly wants to be able to wear come summer. The following claims formed the basis for the inquiry:

"A clinical study shows it helps you burn more fat and lose more weight than just cutting calories alone."

"Yoplait Light. Burn more fat. Lose more weight."

At the end of the commercial, the hanger is shown to be empty as the woman is seen in a convertible automobile adjusting the shoulder strap of her yellow polka bikini that she now she presumably has lost enough weight to wear.

Advertiser's Position:

In response to NAD's inquiry, the advertiser maintained that its claims are fully substantiated by competent and reliable evidence. As support, it cited to the results of a clinical study by Dr. Michael Zemel testing Yoplait Light Yogurt as part of a weight loss plan (the "Zemel study"), and to a large body of scientific evidence about dairy foods and calcium and their connection to weight management.¹

The advertiser explained that Dr. Zemel's controlled, randomized study involved 34 participants who were assigned to two reduced calorie dietary regimens for 12 weeks: a control diet consisting of a 500 calorie per day reduction and 0-1 servings of dairy products/day and 400-500 mg calcium/day) or a yogurt diet, consisting of a 500 calorie per day reduction, 3 daily 6 oz. servings of Yoplait Light Yogurt (totaling 600 mg calcium), resulting in a 1100 mg/day total calcium intake.² The advertiser noted that while all the participants lost weight and body fat due to the caloric reductions in both diets, the yogurt diet group lost significantly more weight (22%), body fat (66%) and trunk fat (81%) than the control diet group, results which are statistically significant and consistent with prior clinical trial results and other scientific evidence.³

¹ The advertiser noted that it also relied on the Zemel study in *General Mills, Inc. (Total Cereal)*, NARB Panel # 121, *NAD Case Reports* (December 2003) ("Total Cereal case").

² The advertiser submitted the study to NAD as confidential.

³ Citing Zemel, M.B., Thompson, W., Milstead, A., Morris, K., Campbell, P., *Dietary calcium and dairy products accelerate weight and fat loss during energy restriction in obese adults*, OBESITY RES. (2004) (in press), which is the study referenced in the Total Cereal case, wherein the group consuming the reduced-calorie, high calcium dairy diet lost more weight, more fat and more trunkal fat than the reduced-calorie, low calcium diet. The advertiser also

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Decision:

In light of the obesity epidemic in the U.S., and growing obesity concerns worldwide, as well as the plethora of food advertising advancing weight loss and related claims, NAD is focusing its monitoring efforts on weight loss related advertisements to ensure that consumers receive truthful and accurate information about a product's weight loss capabilities. Cognizant of the existing and growing scientific research concerning the promising role that calcium, in supplement or dietary form, plays in improving the efficacy of various weight loss regimens, NAD evaluated the sufficiency of scientific studies to support the challenged claims.

"A clinical study shows it helps you burn more fat and lose more weight than just cutting calories alone."; "Yoplait Light. Burn more fat. Lose more weight."

It is well-settled that establishment claims are claims that promise that clinical studies have proven the "purported performance capabilities of a given product, particularly in cases involving statements that allege physical and/or mental benefits" must be supported by "reliable and well controlled clinical testing⁴ on that product that can be readily verified. Specifically, testing should be conducted on the actual product itself, with the same components and percentages of the elements that comprise the product, and the conclusions should support the claims as communicated in the advertising. The test population should also be representative of the population targeted by the advertiser's campaign, demonstrating clinically significant results."⁵

In this case, the advertiser provided a confidential report on clinical testing conducted by Dr. Michael Zemel testing the impact that its Yoplait Light Yogurt product had on weight loss when included as part of a low calorie diet. NAD examined the methodology, execution and results of the confidential Zemel study to determine whether it constituted "competent and reliable" evidence to support the challenged claims. The dietary (including calcium intake) and lifestyle regimens of the 34 obese subjects (Body Mass Index ("BMI") 30 and over) were assessed and monitored prior to and during the study to establish suitability for and compliance with the study,

referred to the citations in *Dietary calcium and dairy products accelerate weight and fat loss during energy restriction in obese adults* as well as Heaney, R.P., *Normalizing calcium intake: Projected population effects for body weight*, 133 J. NUTR. (2003), at 268S-270S; Teegarden, D., *Calcium intake and reduction in weight or fat mass*, 133 J. NUTR. (2003), at 249S-251S; Heaney, R.P., Davies, K.M., Barger-Lux, J., *Calcium and weight: clinical studies*, 21 J. AM. COLL. NUTR. (2002), at 152S-155S.

⁴ NAD noted that it uses its discretion to assess the evidentiary burden required of an advertiser on a case-by-case basis and that it tries to harmonize its decisions with those of the FTC and the courts. See Colgate-Palmolive Company (Simply White Whitening Gel), Report # 4089, *NAD Case Reports* (October/November 2003) (so stating in response to a challenger's contention that NAD has historically required two studies to support a "clinically proven claim," citing court cases and NAD cases where there is no such unequivocal requirement—for e.g., Removatron International Corporation and Frederick E. Goodman V. Federal Trade Commission, 884 F.2d 1489 (1st Cir. 1989); The Procter & Gamble Company (Thermacare Heat Wrap), Report # 4044, *NAD Case Reports* (June/July 2003); Discuss Dental, Inc. (Zoom! Chairside Tooth Whitening System), Report # 4009, *NAD Case Reports* (February 2003); and Den-Mat Corporation (Rembrandt Whitening Toothpaste), Report # 3075, *NAD Case Reports* (December 1993)).

⁵ Bio-Foods, Inc. (Balance™ Nutrition Bars), Report # 3440, *NAD Case Reports* (February 1, 1998).

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whose guidelines followed internationally recognized dietary standards. These controls, in addition to the randomized administration of the control and yogurt diets, ensured the reliability of the statistically significant results referenced above, results which are similar to those in the Zemel study referenced in the Total Cereal case.⁶ The study's results showed that the yogurt diet group lost significantly more weight, body fat and trunk fat than the control diet group (22%, 66% and 81%, respectively). Accordingly, NAD determined that the advertiser had produced sufficiently competent and reliable evidence to substantiate its express claims ("A clinical study shows it helps you burn more fat and lose more weight than just cutting calories alone" and "Yoplait Light. Burn more fat. Lose more weight.").

Summary of Conclusions:

NAD determined that the advertiser had substantiated its express establishment and weight loss claims ("A clinical study shows it helps you burn more fat and lose more weight than just cutting calories alone" and "Yoplait Light. Burn more fat. Lose more weight.") based on the clinically significant results of the Zemel study that tested Yoplait Light Yogurt as part of a weight loss plan.

Advertiser's Statement:

General Mills is pleased with NAD's finding that the weight loss claims in our Yoplait Light yogurt advertising were fully substantiated by clinically significant test results.
(#4174 AMU, closed 04/22/04)

⁶ In that study, the dairy-rich diet of 32 subjects increased fat loss by 64% (61% in the present study) and trunk fat loss by from 19% to 66% (here, 26% to 60%).